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Proposal for a Novel Foods Framework Regulation 2008

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Report Highlights:
On January 14, 2008, the European Commission presented its proposal to revise the current rules on novel foods. The proposal covers foods that have been produced using new techniques (such as animal cloning) and new technologies (such as nanotechnology) and foods which have a safe history of use in third countries (such as noni juice). Only foods included in the "Community list of novel foods" will be allowed on the EU market. Given the political sensitivity that is already surrounding the animal cloning issue, adoption of the novel foods proposal could be a lengthy process.

Includes PSD Changes: No
Includes Trade Matrix: No
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Proposal for a New Novel Foods Framework Regulation

Scope

On January 14, 2008, the European Commission presented its proposal to revise the current EU rules on novel foods laid down in Regulation 258/97. The proposal clarifies and updates the existing definitions and establishes rules for a centralized authorization procedure, labeling, control and use of novel foods. Under the proposal, only novel foods included in the "Community list of novel foods" may be marketed in the EU. The main objectives of the proposal are to simplify the existing authorization procedure and to encourage innovation in the food industry. The proposal covers foods that have been produced using new techniques (such as animal cloning) and technologies (such as nanotechnology) and foods which have safe history of use in third countries but have no tradition of consumption in the EU (such as noni juice). It also sets out data protection rules. The draft regulation does **not** apply to food additives, flavorings, extraction solvents, food enzymes, vitamins and minerals and genetically modified food falling within the scope of Regulation 1829/2003.

The proposal can be downloaded from the Commission's website at http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2007:0872:FIN:EN:PDF.

Definitions

Article 3 defines a novel food as "a food that has not been used for human consumption to a significant degree before May 15, 1997", the date on which Regulation 258/1997 entered into force. If a food has been used exclusively as or in a food supplement before May 15, 1997, it may continue to be used as a food supplement. However, a food's history as a food supplement will not be taken into account to demonstrate "significant consumption" for new food uses. Under the proposal, new uses of the food concerned need a novel food authorization.

The proposal also defines foods that have been produced using new techniques (such as animal cloning) and new technologies (such as nanotechnology) as novel.

The definition of a novel food now also includes foods that are relatively unknown in the EU but which have a history of safe use in third countries (such as noni juice). If the history of safe food use in the country of origin has been demonstrated and the Member States and the European Food Safety Authority (EFSA) do not raise any safety objections, the food can be marketed in the EU after a pre-market notification period.

New Authorization Procedure

The proposal introduces a centralized EU-level authorization procedure whereby all novel food applications are submitted to the European Commission and then directed to EFSA. National administrative procedures will be abolished. The inclusion of a novel food in the Community list of novel foods will depend on EFSA's scientific risk assessment. The "European Group on Ethics in Science and New Technologies" will also be consulted for advice on ethical issues relating to novel foods. The final decision on the inclusion of a novel food in the Community list will be taken by the Commission through the Comitology procedure (see below: "Adoption of the Proposal"). For food safety reasons, post-market monitoring requirements may be imposed.

The same "one key – one door" approach is being proposed for novel foods as for food additives, food enzymes and food flavorings (more information in GAIN report E36113). This means that an applicant can make a single application for approval covering all the possible

food uses of a substance. If the application is approved, all the relevant Community lists regulated under various regulatory frameworks will be updated to include the substance in question.

A simplified procedure applies to traditional foods from third countries which have no history of consumption in the EU. Food operators must send the Commission a notification indicating the name and composition of the food and country of origin. The history of safe use in the country of origin must be documented and will be submitted to EFSA and the Member States. If EFSA and the Member States do not raise any objections within four months, the food may be marketed in the EU within five months from the date of the notification.

Data Protection

Data protection provisions are also included in the proposal. On request by the applicant, newly developed scientific evidence and proprietary data may not be used for the benefit of another application during a five-year period.

Labeling

Novel foods are subject to the EU's general labeling requirements laid down in Directive 2000/13/EC. The inclusion of a novel food in the Community list may impose specific labeling obligations. In certain cases, additional labeling information will be required regarding the description of the food, its source or its conditions of use. Nutrition and health claims regarding novel foods must comply with the rules set out in Regulation 1924/2006 (Nutrition and Health Claims Made on Foods).

Community List of Novel Foods

Within six months from the date of entry into force of the regulation, the Commission will establish a Community list of novel foods. Novel foods already authorized under Regulation 258/97 will be included in the list. The entry of a novel food in the Community list will include a specification of the food, the conditions of use, additional labeling requirements and/or a post-market monitoring requirement. A dedicated webpage on the Commission's website will list the traditional foods from third countries that may be marketed in the EU.

Adoption of the Proposal

This proposal for a new framework regulation has to be adopted under the co-decision procedure. Under the co-decision procedure the Council and the European Parliament have equal legislative power. If the two institutions cannot agree on a proposal, it is put before a conciliation committee.

Implementing measures will be adopted by the Commission under the Comitology procedure. Under the Comitology procedure, the Commission submits a proposal to the Standing Committee on the Food Chain and Animal Health (composed of Member State experts) which votes for or against the proposal on the basis of qualified majority.

Although EFSA has not yet delivered a final opinion on foods derived from cloned animals, the novel foods proposal already covers such products. According to the Commission's spokesperson, the novel foods proposal only outlines the procedure (Comitology) for considering cloned foods. The Commission would wait for the final opinion of EFSA (expected in May 2008), the outcome of the Eurobarometer survey (public opinion poll) and the opinion

of the European Group on Ethics in Science and New Technologies to "reflect on possible measures to be taken".

Given the bad press on animal cloning (the term "Frankenfoods" made its reappearance) and the political sensitivity already surrounding the issue, adoption of the novel foods proposal could be a very lengthy process. Both the Council and the European Parliament will discuss the proposal in the coming months which means that considerable changes may be made. At this point in time it is impossible to predict a timeline for the adoption of the proposal.

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Related reports from USEU Brussels:

Report Number	Title	Date Released
E48006	EFSA releases draft opinion on animal cloning	Jan 2008
E36113	Package of proposals for new legislation on food additives, enzymes and flavorings	Aug 2006
E47056	Food and Agricultural Import Regulations and Standards (FAIRS)	Jul 2007
E47043	Introduction to EU Institutions	Jun 2007
These reports can be accessed through our website http://useu.usmission.gov/agri or through the FAS website http://www.fas.usda.gov/scriptsw/attacherep/default.asp.		